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FILED
APR 12 1993

No. 92-1505

In The

Supreme Court of the United States

October Term, 1992

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY; ROBERT L. KENNEDY,

Respondents.

Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Ninth Circuit

BRIEF IN OPPOSITION

MICHAEL M. ESSMYER
MICHAEL M. ESSMYER & ASSOCIATES
4300 Scotland
Houston, Texas 77007
(713) 868-1111
(713) 863-9334 (FAX)

Attorneys for Respondents

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

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QUESTIONS PRESENTED

In reversing summary judgment below, the Ninth Circuit held that the affidavit of a certain physician established the existence of a genuine issue of material fact regarding causation and was sufficient to preclude summary judgment. The court noted that petitioner had not presented any controverting evidence as to the physician's reliability or methodology and had not contested admissibility of his testimony, and specifically rejected petitioner's argument that the affidavit showed causation based solely on a "temporal relationship."

I. In reversing the district court's granting of summary judgment, did the court of appeals properly find that the evidence established the existence of a genuine issue of material fact regarding causation, sufficient to preclude summary judgment?

II. Is a physician's uncontroverted opinion of causation based on reasonable medical probability insufficient as a matter of law due to the non-existence of epidemiological studies?

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BRIEF IN OPPOSITION

Respondents respectfully request this Court to deny the Petition for Writ of Certiorari to review the judgment and opinion of the United States Court of Appeals for the Ninth Circuit, entered in this proceeding on September 8, 1992.

OPINIONS BELOW

Respondents rely upon petitioner's recitation of the Opinions below.

JURISDICTION

Respondents agree with petitioner that jurisdiction, if it exists, is under 28 U.S.C. Sec. 1254 (1). As this is an appeal from the denial of a summary judgment by the Ninth Circuit Court of Appeals' reversal of the summary judgment granted below, arguably there is no appealable judgment.

STATEMENT OF THE CASE

Petitioner Collagen Corporation's statement of the case is argumentive and misleading. For this reason, Respondents submit the following.

This Petition arises from the reversal of a summary judgment on motion for rehearing to the Ninth Circuit Court of Appeals. Respondents filed a products liability lawsuit against Petitioner Collagen Corporation, seeking damages for personal injuries caused by use of petitioner's injectable medical device, Zyderm.

Petitioner filed a motion for summary judgment in the district court, alleging lack of evidence that Zyderm caused Respondent Charlotte Kennedy's injuries. In opposing the motion, Respondents filed the affidavit of Dr. Joseph Spindler, an immunologist and rheumatologist, who testified as to his examination and testing of Respondent Charlotte Kennedy, and that based on reasonable medical probability, the Zyderm injections caused her autoimmune injuries.

Petitioner did not present any controverting affidavits or opinion testimony to refute the grounds for

causation alleged in the affidavit, or to show that the affidavit was inadmissible. There was absolutely no testimony that Dr. Spindler's methodology or basis for his opinion were unreliable, or that he was not a credible expert. While petitioner attempts to argue that Dr. Spindler's affidavit alleged only a "temporal association" as grounds for causation, this contention was specifically rejected by the Ninth Circuit, which correctly pointed out the existence of other factors in the affidavit.

With its Petition for Writ of Certiorari, petitioner is requesting this Court to rule that the uncontroverted affidavit was insufficient as a matter of law, and that it could not have been sufficient without epidemiological studies to support causation. It is undisputed that no epidemiological studies existed on either side of the causation issue.

REASONS TO DENY THE PETITION

I.

The Ninth Circuit's opinion is an application of settled law to the particular facts of the case, and is otherwise without general interest, significance or importance.

The unpublished opinion from which petitioner seeks writ of certiorari is limited to its particular facts, and does not stand as a case of general interest or importance. There is no meaningful conflict between this decision and those from other circuits, and as petitioner never presented controverting evidence contesting reliability or admissibility of the causation evidence, this Petition is

inappropriate for resolving any disputes over standards for admissibility or reliability of expert testimony.

The Ninth Circuit correctly reversed summary judgment below based on *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. 1984), *cert. denied*, 469 U.S. 1062 (1984). This case is not one involving "novel scientific methodologies," and the issues raised by *Daubert* do not apply.

II.

Daubert is inapplicable to this petition.

Petitioner alleges this case to be substantially the same as *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, No. 92-102. Respondents agree with the Ninth Circuit court that *Daubert* does not apply to this case. In *Daubert*, the court relied on specific factual findings as to what constituted generally accepted scientific methodology as to the disputed testimony, and on the large volume of unfavorable epidemiological studies establishing the absence of causation. Here, petitioner presented no facts contradicting Dr. Spindler's testimony, and there were no epidemiological studies in existence.

Regardless, writ has been granted in *Daubert*, and granting of this Petition would be redundant. Moreover, as this is a case reversing and denying summary judgment, arguably there is no basis for review by this Court.

III.

Petitioner did not present testimony to refute or controvert the reliability or admissibility of Respondents' expert witness testimony below.

The Ninth Circuit properly reversed summary judgment on the basis of Dr. Spindler's affidavit, and in that the admissibility and reliability of his opinion testimony had not been controverted or refuted by petitioner in the district court.

> [I]n determining . . . whether the informational basis of an expert opinion is of a type reasonably relied upon by experts in the field, the proper inquiry is not what the court deems reliable, but what the experts in the relevant discipline deem it to be.

In re Paoli Railroad Yard PCB Litigation, 916 F.2d 829, 853 (3rd Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991) (citations omitted). Had Petitioner Collagen Corporation followed proper procedures and presented controverting testimony as to reliability and admissibility, the district court might have been required to hold a hearing on the issues of reliability and admissibility. *See DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990) (reversing district court's granting of summary judgment in absence of a record-supported factual finding that plaintiff's doctor relied upon data not regarded as reliable by experts in the field.) However, petitioner did *not* present any controverting testimony as to the reliability or admissibility of Dr. Spindler's opinion.

This is not a case involving "novel scientific methodologies." Respondents were not required to present epidemiological studies suggesting causation, as no such

studies existed and petitioner did not present any statistical evidence refuting causation. A physician's opinion of causation based on reasonable medical probability and uncontroverted methodologies or bases is not rendered insufficient as a matter of law due to the non-existence of epidemiological studies.

In arguing that any opinion of "reasonable medical probability" must be based upon epidemiological evidence, *even where epidemiological studies refuting causation do not exist*, petitioner seeks to impose a standard of summary judgment proof that simply does not exist. Petitioner relies on several *Bendectin* litigation opinions, which involve a pharmaceutical drug having the benefit of over thirty published studies. It is undisputed that no studies existed for the Zyderm product made the basis of this lawsuit, either tending to prove or disprove causation. (Subsequent to the summary judgment below, the FDA issued its finding of a statistically significant association between Zyderm injections and two autoimmune diseases. Respondent Charlotte Kennedy's primary injury from Zyderm had been SLE, an autoimmune disease.)

Petitioner would have this Court hold that "reasonable medical probability" cannot exist absent published, peer-reviewed studies affirming scientific causation. The district court properly rejected this argument, citing *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984) and related cases. The courts simply do not recognize petitioner's argument.

IV.

Petitioner cannot use this Petition to present "evidence" of what immunology experts would consider "reliable" or "credible" evidence.

In an apparent recognition of what it failed to do at trial level, Petitioner Collagen Corporation attempts in its Petition to fashion some type of medical argument against Dr. Spindler's affidavit by citing medical and scientific treatises. These treatises were not presented as summary judgment evidence, are not in the record, and have no significance. This Court is not required to sift through medical and scientific writings and reach a unilateral determination of whether Dr. Spindler's testimony carries medical and scientific credibility or reliability, particularly where petitioner failed to present controverting evidence below.

These are matters which should have been raised during the original summary judgment proceeding through properly-presented expert testimony. As petitioner failed to do so, these arguments have long been waived.

CONCLUSION

For the foregoing reasons it is respectfully submitted that this petition for writ of certiorari should be denied.

Respectfully submitted,
MICHAEL M. ESSMYER
MICHAEL M. ESSMYER & ASSOCIATES
4300 Scotland
Houston, Texas 77007
(713) 868-1111
(713) 863-9334 (FAX)

Attorneys for Respondents